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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,343	01/31/2001	John T. McDevitt	5119-00529/EBM	7209

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/775,343

Applicant(s)

MCDEVITT ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 309,311-321 and 323-340 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 309,311-315,317-321 and 323-340 is/are rejected.  
7) ☒ Claim(s) 316 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 March 2005 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed 22 March 2005 in which claim 309 was amended. The amendments have been thoroughly reviewed and entered.

The previous objections and rejections in the Office Action dated 22 November 2004 are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection are discussed.

Claims 309, 311-321, 323-340 are under prosecution.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 309, 311, 313-315, 317-321, 323, 325, 329, 330, 333, 335, 337-339 are rejected under 35 U.S.C. 102(e) as being anticipated by Alberte (U.S. Patent No. 6,692,696, filed 18 June 1998).

Regarding Claim 309, Alberte discloses a system comprising a body, a light source disposed within the body (# 36), a cartridge (#28), wherein the cartridge is removable and positionable within the body (Column 21, lines 50-62), wherein the cartridge comprises a body (#30) and a sensor array (#12, Fig. 7) wherein the array comprises a supporting member and at least one cavity within the supporting member (stage #32), a particles positioned in the cavity (e.g. binding agent, cells or GPCR), a detector disposed within the body configured to detect a single from analyte interaction such that the light source and the detector are positioned such that light passes from the light source to the particle and onto the detector (Fig. 1-7, Column 2, line 50-Column 22, line 65). Alberte further teaches the device wherein the cavity is configured by adding a binding agent (e.g. hydrogel) such that the particles (GPCR-containing cells) are contained within the cavity during use (Column 22, line 34-40 and 56-64).

Regarding Claim 311, Alberte discloses the system further comprising a sample input port positioned on the body and coupled to the sensor (Column 22, line 66-Column 23, line 43).

Regarding Claim 313, Alberte discloses the system further comprising a sample input port and filter positioned on the body and coupled to the sensor (Column 23, lines 22-25).

Regarding Claim 314, Alberte discloses the system further comprising a fluid cartridge coupled to the body and array i.e. flow chamber #22 (Column 21, line 66-Column 22, line 8).

Regarding Claim 315, Alberte discloses the system further comprising an electronic controller disposed in the body and coupled to the sensor, light source and detector e.g. batteries coupled to the detector and light source (Column 24, line 7-25)

Regarding Claim 317, Alberte discloses the system further comprising a data transfer system e.g. microprocessor (Column 24, lines 32-56).

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Regarding Claim 318 Alberte discloses the system wherein the detector comprises a monochrome detector (Column 24, lines 26-29).

Regarding Claim 319 Alberte discloses the system wherein the detector comprises a color detector i.e. fluorescence photo detector (Column 24, lines 8-29).

Regarding Claim 320, Alberte discloses the system wherein the light source comprises at least one light-emitting diode (Column 23, lines 48-51).

Regarding Claim 321, Alberte discloses the system wherein the light source comprises a light-emitting diode (Column 23, lines 48-51).

Regarding Claim 323, Alberte discloses the system comprising a fluid delivery system e.g. propeller or pump (Column 23, lines 2-7).

Regarding Claim 325, Alberte discloses the system wherein the particle comprises a receptor molecule coupled to a polymeric resin (Column 22, lines 56-65).

Regarding Claim 329, Alberte discloses the system wherein the particle (cell) comprises a first (GPCR-labeled w/fluorescent chromophore, Column 26, lines 57-67) and second indicator (Ca<sup>++</sup> channel) coupled to the receptor (GPCR) such that in the presence of analyte causes indicators to interact (Ca<sup>++</sup> flux) to produce a signal (Column 20, lines 55-65).

Regarding Claim 330, Alberte discloses the system wherein the particles (cells) comprise an indicator (Ca<sup>++</sup>) wherein the indicator is associated with a receptor (GPCR) such that in the presence of analyte the indicated is displace to produce a signal (Column 20, lines 55-65).

Regarding Claim 333, Alberte discloses the system wherein the supporting member further comprises a barrier layer over the cavity to inhibit dislodgement of the particle (i.e. membrane, Column 21, lines 63-67 and #18, Fig. 7).

Regarding Claim 335, Alberte discloses the supporting member comprises plastic (Column 21, lines 57-59).

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Regarding Claim 337, Alberte discloses the system wherein the cavity is configured such that fluid passes through the cavity (see arrows illustrating fluid flow, Fig. 1-5).

Regarding Claim 338, Alberte discloses the system further comprising a pump coupled to the supporting member (Column 23, lines 2-7).

Regarding Claim 339, Alberte discloses the system wherein a channel is formed in the supporting member coupled to a pump (see arrows, Fig. 1-5 and Column 23, lines 2-7).

### **Response to Arguments**

5. Applicant points to the specification for a teaching of the claimed "particles" and the cavity configuration as newly claimed. Applicant asserts that Alberte does not teach the claimed particles and cavity configuration because the G-Protein Coupled Receptor of Alberte is not encompassed by the claimed particle and cartridge configuration as described in the specification. The arguments have been considered but are not found persuasive. The instant specification defines a particle as a receptor molecule e.g. protein. Hence, the GPCR-containing cells of Alberte are encompassed by the claimed particle.

A particle, in some embodiments, possess both the ability to bind the analyte of interest and to create a modulated signal. The particle may include receptor molecules which possess the ability to bind the analyte of interest and to create a modulated signal. Alternatively, the particle may include receptor molecules and indicators. The receptor molecule may possess the ability to bind to an analyte of interest. Upon binding the analyte of interest, the receptor molecule may cause the indicator molecule to produce the modulated signal. The receptor molecules may be naturally occurring or synthetic receptors formed by rational design or combinatorial methods. Some examples of natural receptors include, but are not limited to, DNA, RNA, proteins, enzymes, oligopeptides, antigens, and antibodies. Either natural or synthetic receptors may be chosen for their ability to bind to the analyte molecules in a specific manner (page 9, lines 9-18)

Furthermore, Alberte specifically teaches the cavity within the cartridge wherein the cavity is configured by application of a binding agent for containing the particle within the cavity such that the particles (GPCR-containing cells) are contained within the cavity during use (Column 22, line 34-40 and 56-64).

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Applicant asserts that Alberte does not teach the first and second indicators as required by Claim 329. The argument has been considered but is not found persuasive because Alberte teaches an embodiment comprising two indicators i.e. a first, GPCR-labeled w/fluorescent chromophore and second, (Ca<sup>++</sup> channel) coupled to the receptor (GPCR) such that in the presence of analyte causes indicators to interact (Ca<sup>++</sup> flux) to produce a signal (Column 20, lines 55-65).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 324, 326-328, 331-332, 334, 336 and 340 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alberte (U.S. Patent No. 6,692,696, filed 18 June 1998) in view of Stabile et al (U.S. Patent No. 5,872,623, issued 16 February 1999).

Regarding Claims 324, 326-328, 331-332, 334, 336 and 340, Alberte discloses a system comprising a body, a light source disposed within the body (# 36), a cartridge (#28), wherein the cartridge is removable and positionable within the body (Column 21, lines 50-62), wherein the cartridge comprises a body (#30) and a sensor array (#12, Fig. 7) wherein the array comprises a supporting member and at least one cavity within the supporting member (stage #32), a particles positioned in the cavity (e.g. binding agent, cells or GPCR), a detector disposed within the body configured to detect a single from analyte interaction such that the light source and the detector are positioned such that light passes from the light source to the particle and onto the detector (Fig. 1-7, Column 2, line 50-Column 22, line 65).

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Alberte does not teach the detector comprises a charge-coupled device; a plurality of particles in a plurality of cavities; wherein the particle ranges from about 0.05 microns to about 500 microns wherein the volume of the particle changes when contacted; wherein the supporting member comprises silicon; a transparent barrier over the cavity to provide a channel; or a dry film photoresist (Column 16, lines 62-67).

However, these elements were well known in the art and routinely practiced as taught by Stabile et al who teach a similar device comprising a substrate having cavities with particles therein, light source and a detector (fig. 1).

Regarding Claim 324, Stabile et al disclose the apparatus wherein the detector comprises a charge-coupled device (Column 3, lines 7-11).

Regarding Claim 326, Stabile et al disclose the apparatus comprises a plurality of particles in cavities and the system is configured to "substantially" simultaneously detect a plurality of analytes i.e. within 1 second (Column 3, lines 62-65).

Regarding Claim 327, Stabile et al disclose the apparatus wherein the particle ranges from about 0.05 microns to about 500 microns (Column 15, lines 40-49).

Regarding Claim 328, Stabile et al disclose the apparatus wherein the volume of the particle changes when contacted with fluid i.e. swells (Column 15, lines 40-49).

Regarding Claim 331, Stabile et al disclose the apparatus wherein the supporting member comprises silicon (Column 16, lines 39-40).

Regarding Claim 332, Stabile et al disclose the apparatus further comprising channels (Column 16, lines 34-59) and having a fluid delivery system as taught by Zanzucchi et al (Column 14, line 54-Column 15, line 3) as defined by Zanzucchi et al teach the system wherein channels are configured for fluid flow (Column 7, lines 14-45).

Regarding Claim 334, Stabile et al disclose the apparatus comprises a transparent barrier over the cavity i.e. window array positioned at a fixed distance (Fig. 4 and Column 10, lines 33-46).



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Regarding Claim 336, Stabile et al disclose the apparatus wherein the supporting member comprising a dry film photoresist (Column 16, lines 62-67).

Regarding Claim 340, Stabile et al disclose the apparatus comprises the fluid delivery system of Zanzucchi et al (Column 14, line 54-Column 15, line 3) as defined by Zanzucchi et al teach the system wherein fluid comprises a vacuum (Column 23, lines 17-32). The fluid system of Stabile et al and Zanzucchi et al comprise a vacuum as required by the instant claim. While the cited passages do not teach the claimed function of the vacuum (i.e. pull fluid) the intended use or function of a structural element does not define the structural element over the prior art.

Stabile et al also teach these elements function together to provide analysis of closely spaced detection sites with spatially resolving measurement for each site (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the elements taught by Stabile et al to the device of Alberte for the expected benefit of providing or the analysis of closely spaced receptor-analyte interaction with spatially resolved measurements for each site at taught by Stabile (Abstract).

#### **Response to Arguments**

8. Applicant reiterates the arguments discussed above regarding Alberte and Claim 309. The arguments have been considered but are not found persuasive for the reasons stated above.

9. Claim 312 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alberte (U.S. Patent No. 6,692,696, filed 18 June 1998) in view of Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996).

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Regarding Claim 312, Alberte discloses a system comprising a body, a light source disposed within the body (# 36), a cartridge (#28), wherein the cartridge is removable and positionable within the body (Column 21, lines 50-62), wherein the cartridge comprises a body (#30) and a sensor array (#12, Fig. 7) wherein the array comprises a supporting member and at least one cavity within the supporting member (stage #32), a particles positioned in the cavity (e.g. binding agent, cells or GPCR), a detector disposed within the body configured to detect a single from analyte interaction such that the light source and the detector are positioned such that light passes from the light source to the particle and onto the detector (Fig. 1-7, Column 2, line 50-Column 22, line 65) but does not teach the fluid delivery system comprise an input port configured to receive a syringe.

Wilding et al teach a similar apparatus comprising a fluid delivery system wherein the system comprises an inlet port configured to receive a syringe wherein the syringe permits reagent delivery while minimizing evaporation of assay components (Column 18, lines 21-30). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the inlet port configuration of Wilding et al to the fluid delivery of Alberte for the expected benefits of providing for reagent delivery while minimizing evaporation of assay components as taught by Wilding et al (Column 18, lines 21-30 and Column 22, lines 57-64).

#### **Response to Arguments**

10. Applicant reiterates the arguments discussed above regarding Alberte and Claim 309. The arguments have been considered but are not found persuasive for the reasons stated above.

#### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

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*Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 309, 311-321, 323-340 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 and 173-174 of copending Application No. 09/287,248. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to very similar systems for detecting an analyte and differ only in the arrangement of the limitations within the claim sets. For example, instant independent Claim 309 is drawn to a cartridge comprising a body, and sensor array comprising a supporting member. In slight contrast of wording, independent Claim 1 of the '248 set is drawn to a sensor array comprising a supporting member and cover and dependent Claims 8-9 further defines the system wherein the supporting member is between a transparent top surface and bottom surface (i.e. cartridge). Hence, the claims sets merely differ in claim language and arrangement of limitations within the claim sets. Therefore the claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 309, 311-321, 323-340 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 413-466, 490-492, 726 and 730 of copending Application No. 09/616,731,248. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of

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claims are drawn to very similar systems for detecting an analyte and differ only in the arrangement of the limitations within the claim sets and further differ in that the '731 system further comprises a vacuum apparatus. However, the open claim language "comprising of the instant claims encompasses the additional element of the '731 system. As such, the claim sets are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **Conclusion**

14. Claim 316 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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BJ Forman, Ph.D.  
Primary Examiner  
Art Unit: 1634  
May 31, 2005